4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket Nos. FDA-2014-D-1584, FDA-2014-D-1696, FDA-2014-D-1856, and FDA-2015-D-3581]

Draft Guidances Relating to the Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance documents entitled "Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry"; "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff"; "Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry"; and "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff." The Agency is taking this action to allow interested persons additional time to submit comments and any new information.

DATES: FDA is extending the comment period on the four draft guidances announced in the Federal Register (see SUPPLEMENTARY INFORMATION). Submit either electronic or written comments by September 27, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-1584 for "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry"; Docket No. FDA-2014-D-1696 for "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff"; Docket No. FDA-2014-D-1856 for "Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry"; or Docket No. FDA-2015-D-3581 for "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of

Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911, lori.olsenchurchyard@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 23, 2014 (79 FR 63348), FDA announced the availability of a draft document entitled "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry" dated October 2014.

In the Federal Register of December 23, 2014 (79 FR 77012), FDA announced the availability of a draft document entitled "Minimal Manipulation of Human Cells, Tissues, and

Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff" dated December 2014.

In the Federal Register of December 24, 2014 (79 FR 77414), FDA announced the availability of a draft document entitled "Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry" dated December 2014.

Following publication of these three notices of availability, FDA received requests to allow interested persons additional time to comment.

In the Federal Register of October 30, 2015 (80 FR 66850), FDA announced the availability of a draft document entitled "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff" dated October 2015.

In the Federal Register of October 30, 2015 (80 FR 66845), FDA announced a public hearing in a notice entitled "Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments".

The draft guidances on same surgical procedure, minimal manipulation, adipose tissue, and homologous use provide recommendations for complying with the regulatory framework for human cells, tissues, and cellular and tissue based products under 21 CFR part 1271 that were to be discussed during the part 15 (21 CFR part 15) hearing. In conjunction with the part 15 hearing and announcement of availability of the homologous use draft guidance, in the Federal Register of October 30, 2015 (80 FR 66847; 80 FR 66844; 80 FR 66849), FDA reopened the comment periods on the same surgical procedure, minimal manipulation, and adipose tissue draft guidances, respectively, to allow potential respondents time to thoroughly evaluate and address

pertinent issues. Comments were requested by April 29, 2016. In this notice FDA is extending the comment period to September 27, 2016.

Elsewhere in this issue of the Federal Register, FDA is announcing the rescheduling of a 2-day part 15 public hearing to September 12 and 13, 2016, to obtain input from stakeholders on the four issued draft guidance documents. In a separate document, FDA is also announcing a public scientific workshop to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products subject to premarket approval, including stem cell-based products.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-09366 Filed: 4/21/2016 8:45 am; Publication Date: 4/22/2016]